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October 25, 2023

VIA ECF
Honorable Robert B. Kugler
United States District Court
Mitchell H. Cohen Building and
U.S. Courthouse
4th and Cooper Streets
Camden, New Jersey 08101

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation*, Case No. 1:19-md-02875-RBK (D.N.J.)**

Dear Judge Kugler:

Please accept this letter on behalf of the Plaintiffs with regard to the upcoming third-party payor economic loss class action trial involving the manufacture and sale of valsartan contaminated by the probable human carcinogens NDMA and NDEA, by the ZHP, Teva, and Torrent Defendants (and their respective US subsidiaries and affiliated entities). This letter is informed by a meet and confer between the parties on October 20, 2023. Plaintiffs look forward to discussing these and other related issues with the Court at the upcoming November 1, 2023 case management conference, and thereafter.

Trial Start Date: Plaintiffs and Defendants are in agreement that a start date, defined as the day the parties give their opening statements, in March 2024 is reasonable, provided that the

class notice and related opt-out process can be completed prior thereto along with any dispositive motion practice (with rulings on dispositive motions not to be issued prior to the end of the class notice request for exclusion date), which Plaintiffs believe should be accomplished. Defendants advised that they are all available in early March. Plaintiffs are available in early, mid, or late March, or early April, depending on the Court's preference.

Trial Duration: Plaintiffs believe that a total duration of 3-5 weeks from opening statements to the start of jury deliberations is a reasonable estimate, but that the expected duration will be dependent on a number of issues, including the issues to be tried following the determination of dispositive and other motions, and the Court's determination of issues that will impact the duration of the trial.

Jury/Non-Jury Trial: Plaintiffs are willing to try this case without a jury, but understand that the Defendants are unwilling to waive a jury.

Jury Unanimity: Plaintiffs believe that a less than unanimous jury verdict is preferable, but understand that the Defendants will ask for a unanimous jury verdict.

Jury Selection/Voir Dire: The parties are in agreement that a detailed questionnaire would be helpful to all parties, and would like to discuss potential modification of the Court's standard practice to allow the parties to obtain more fulsome information in advance of the actual jury selection process. This would include potentially bringing the panel to Court prior to jury selection to address hardship excuses at that time, and for the remaining members of the panel to complete the questionnaires at that time. This would allow the parties to review the questionnaires in advance, identify obvious cause challenges, determine what questions require follow up with jurors in advance, and identify jurors who should be questioned outside the hearing of the rest of the panel to avoid embarrassment and tainting the panel.

Peremptory Challenges: Plaintiffs will request additional peremptory challenges to balance the number of peremptory challenges held by the Defendants.

Answer: Defendants have indicated that they will file Answers shortly, and do not expect to file any cross-claims. Plaintiffs submit that Answers should be filed no later than 2 weeks prior to the deadline for the filing of dispositive motions.

Dispositive/Summary Judgment Motions: The parties agree that dispositive motions/Summary Judgment motions should be filed simultaneously. Plaintiffs may seek to file motions for partial summary judgment (not to be decided until the end of the class notice request for exclusion date), including but not limited to, seeking Court determinations that (1) each of the Defendants is liable for its breaches of express and implied warranty, and as part of that motion (a) determining that general causation of cancer is not an element of any claim that needs to be determined in this TPP economic loss class trial; instead, to the extent the Court deems necessary, that the contamination presented an "unreasonable safety or health risk," or "unacceptable carcinogenic risk" (as stated by ZHP, for example, in its recall notices) or a variation thereof, which can be determined by the Court as a matter of law and undisputed fact, and (b) to the extent the Court finds that cGMP violations need to be established (Plaintiffs' position is that this is not necessary on the claims to be tried), a determination that the ZHP, Teva, and Torrent Defendants violated cGMPs in the manufacture, distribution, and sale of their at issue VCDs as a matter of law; (2) the at issue VCDs sold by the ZHP, Teva, and Torrent Defendants were adulterated, as a matter of law (and any related findings of law and fact); and (3) that the ZHP, Teva, and Torrent Defendants each are liable for violating the applicable consumer protection laws with respect to their distribution and sale of their adulterated VCDs.

Plaintiffs propose that the parties be required to simultaneously file their dispositive motions on a date to be determined after the Court sets a trial date, with responses to be filed simultaneously within 21 days thereafter, and limited replies 10 days thereafter.

Motions *in limine*: Plaintiffs intend to file MILs, and anticipate filing at least the following: (1) motion to preclude Defendants from blaming one another, including a settling co-Defendant, (2) motion to preclude Defendants from blaming the FDA in any way, or suggesting that the FDA approved the contaminated valsartan, (3) motion to preclude Defendants from pointing to other companies that produced contaminated valsartan for any purpose including to excuse their conduct, (4) motion to preclude Defendants from asserting that the contaminated valsartan had economic or other value since it controlled blood pressure as intended since that is not the question presented where they sold a drug that was contaminated with a probable human carcinogen, was adulterated, and should not have been sold, (5) motion to preclude Defendants from asserting the cost of replacement drugs, since that is not a question presented by the claims to be tried, (6) motion to preclude Defendants from arguing that their VCDs were not in fact adulterated despite the regulatory determinations by the FDA and the undisputed fact that they were contaminated with NDMA and NDEA, and (7) motion to preclude Defendants from arguing that Plaintiffs' damages should be reduced or offset by asserted reimbursements from collateral sources.

***Daubert* Motions on Damages Experts:** Plaintiffs intend to file motions to exclude certain or all of Defendants' damages experts. Related, Plaintiffs have reviewed data produced by the retailer defendants and propose to ask their damages expert to provide a short supplemental report addressing that data, and have asked the retailers if they have any objection, and are awaiting a firm response.

Deposition Designations: Plaintiffs anticipate that a substantial portion of the trial will involve submission of video deposition testimony to the jury. Plaintiffs propose that the exchange of deposition designations of company witnesses (30(b)(6) and fact witnesses) proceed on a rolling basis, beginning within 10 days and that Defendants be required to provide counter-designations and objections within 21 days of receipt of Plaintiffs' designations, with Plaintiffs providing counter-counter designations and objections to Defendants' counter-designations within 14 days thereafter. Plaintiffs propose (and believe Defendants agree) that as disputes are identified, and in particular as to issues that are likely to recur in multiple depositions, that the disputes be submitted to the Court on a rolling basis for decisions. This will provide critical guidance to the parties, allowing the parties to proceed more efficiently once they know and understand the Court's rulings.

Plaintiffs also seek Defendants' agreement (or the Court's determination in the absence of agreement) that Defendants' counter designations will only be included and played to the jury during Plaintiffs' direct case to the extent necessary for "completeness." This is consistent with New Jersey and Federal law. This will prevent Defendants from counter-designating large portions of a witness's deposition testimony beyond what is designated by Plaintiffs, causing Plaintiffs' case to be artificially extended and complicated, and making it much harder if not impossible for the jury to discern which testimony Plaintiffs intended to communicate, since that would be lost in the mass of testimony Defendants would counter-designate. Defendants can call their own witnesses on their case.

Exhibit List: A deadline will be needed for the exchange of exhibit lists, and discussion of any issues arising therefrom. The parties should meet and confer on the form of exhibit lists and submit a proposal to the Court, subject to the Court's preferences.

Stipulations: The parties have not discussed stipulations. It is expected that stipulations can be reached as to the admissibility of evidence and facts that cannot be reasonably disputed.

Pending Motions: At present the *Daubert* motions regarding the liability experts remain pending. Depending on the Court's rulings on the legal issues to be presented a number of the experts, and/or significant parts of their testimony will not be permitted and/or necessary at trial. In addition, Plaintiffs' motion for Rule 37 sanctions against ZHP remains pending. The relief requested would likely impact the scope of issues to be tried, if granted.

Plaintiffs reserve the right to supplement or modify the positions stated herein.

Thank you for your courtesies and consideration.

Respectfully,

ADAM M. SLATER

Cc: Counsel of record (via ECF)